



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,630	08/17/2006	Chika Itoh	P28519	6182
7055 7590 07/06/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER CHO, JENNIFER Y	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 07/06/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,630	ITOH ET AL.	
	Examiner	Art Unit	
	Jennifer Y. Cho	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Acknowledgment is made of the Information Disclosure Statement filed 3/29/2007.

Claim Rejections – 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being confusing, because of the "acyl group" description for the R¹CO and R²CO groups. It is unclear whether the groups are either ketone or ester functionalities. Appropriate clarification is requested. The Examiner suggests that the Applicant's amend the claims to read R¹CO₂ and R²CO₂ in the text and within the structure diagram.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

Art Unit: 1621

subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

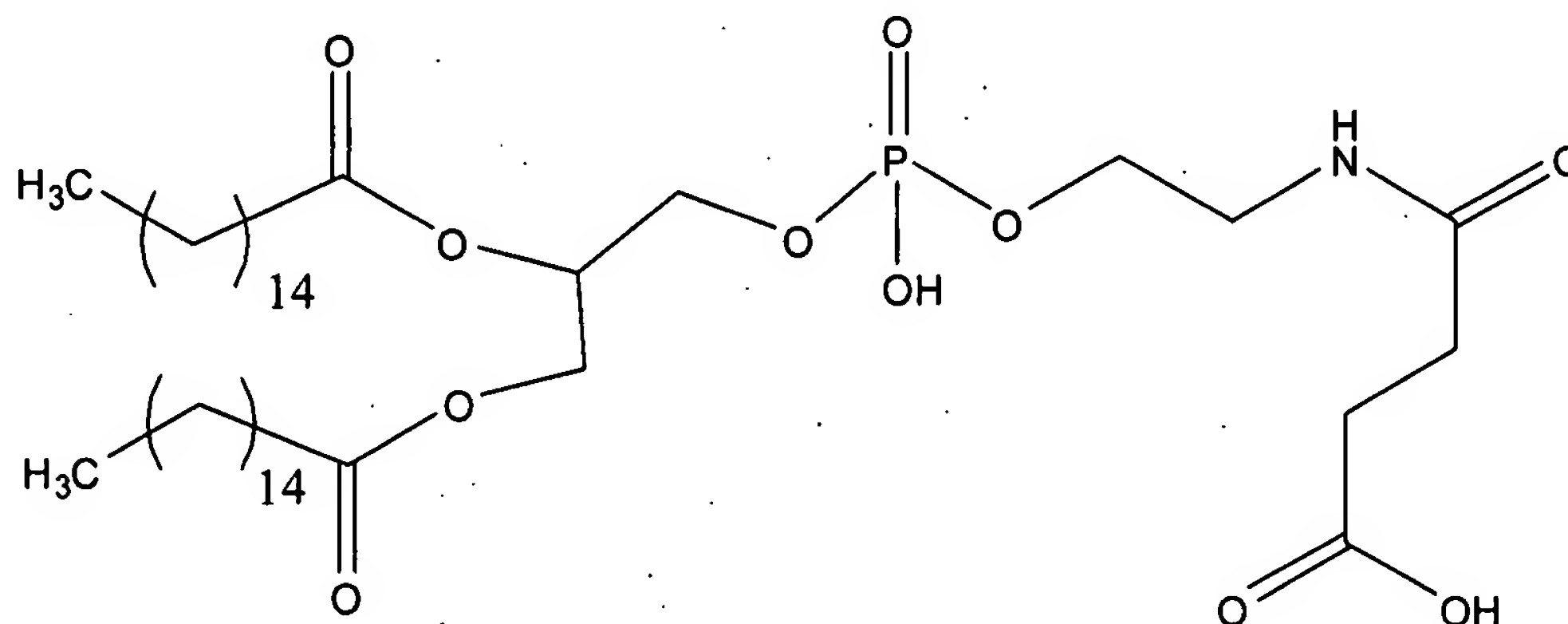
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Wronski et al. (US 2002/0147136).

The instant claims are drawn to a phospholipid derivative containing polyoxyalkylene groups, as well lipid membrane structures, pharmaceutical compositions and surfactants containing the phospholipids derivative.

Von Wronski et al. teaches a N-Glutaroyl-dipalmitoyl phosphatidyl ethanolamine, Compound 1 (page 46; page 48, section 467, lines 1-2), which is a distearoylphosphatidylethanolamine (page 12, section 127, lines 17-18). This phospholipid derivative can be made into liposomes (lipid membranes) with polyoxyethylene fatty acid esters and polyoxyethylene fatty alcohol ethers (page 12, section 127, 6-7 lines from the bottom page). In addition, similar compounds to polyoxypropylene glycol and polyoxyethylene glycol can be added to the phospholipids for a mixture to form surfactants (page 16, section 146, lines 1-6). Furthermore, polyoxypropylene and polyoxyethylene can be added, along with polyoxyethylene fatty acid esters, to form surfactants (page 17, section 152, 1-3 and 12-14 lines from the

bottom page). These compounds are particularly suitable for incorporation into lipid membranes (page 18, section 168, lines 5-6) and incorporated into pharmaceutical compositions (page 4, section 41, lines 12), with antitumor agents (page 4, section 41, lines 1-3; page 1, section 2, lines 3-4).



Compound 1

Ueno et al. is deficient in the sense that it does not explicitly state the ratio of oxyethylene groups to oxyalkylene groups, the ratio of oxyethylene groups to oxyethylene groups and oxypropylene groups, the weight ratio or the average molar number of the oxyalkylene groups.

However, it is the position of the Examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the ratio of oxyethylene groups to oxyalkylene groups, the ratio of oxyethylene groups to oxyethylene groups and oxypropylene groups, the weight ratio or the average molar number of the oxyalkylene groups. Thus it would be obvious in the process to form the phospholipids composition to optimize the ratios and weights of the added oxyalkylene

Art Unit: 1621

groups. The Applicant does not show any unusual and/or unexpected results for the limitation stated. Note that the prior art provides the same effect desired by Applicant, the formation of phospholipids derivatives for the pharmaceutical industry.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use the appropriate ratios of oxyethylene groups to oxyalkylene groups, ratios of oxyethylene groups to oxyethylene groups and oxypropylene groups, weight ratios and average molar numbers for the oxyalkylene groups. The expected result would be the efficient production of phospholipids derivative containing polyoxyalkylene groups for use as lipid membranes, surfactants and pharmaceuticals.

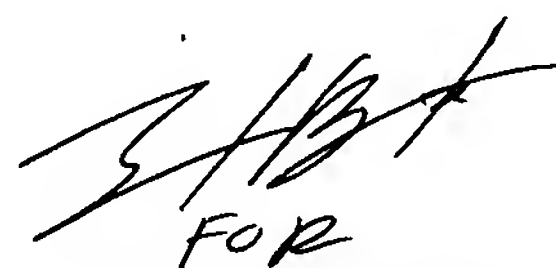
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272 0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

A handwritten signature in black ink, appearing to read "J. Richter", with the word "FOR" written in smaller letters below it.

Johann Richter
Supervisory Patent Examiner
Technology Center 1600